

## MEETING ABSTRACT

## Open Access

## VISTA Trials

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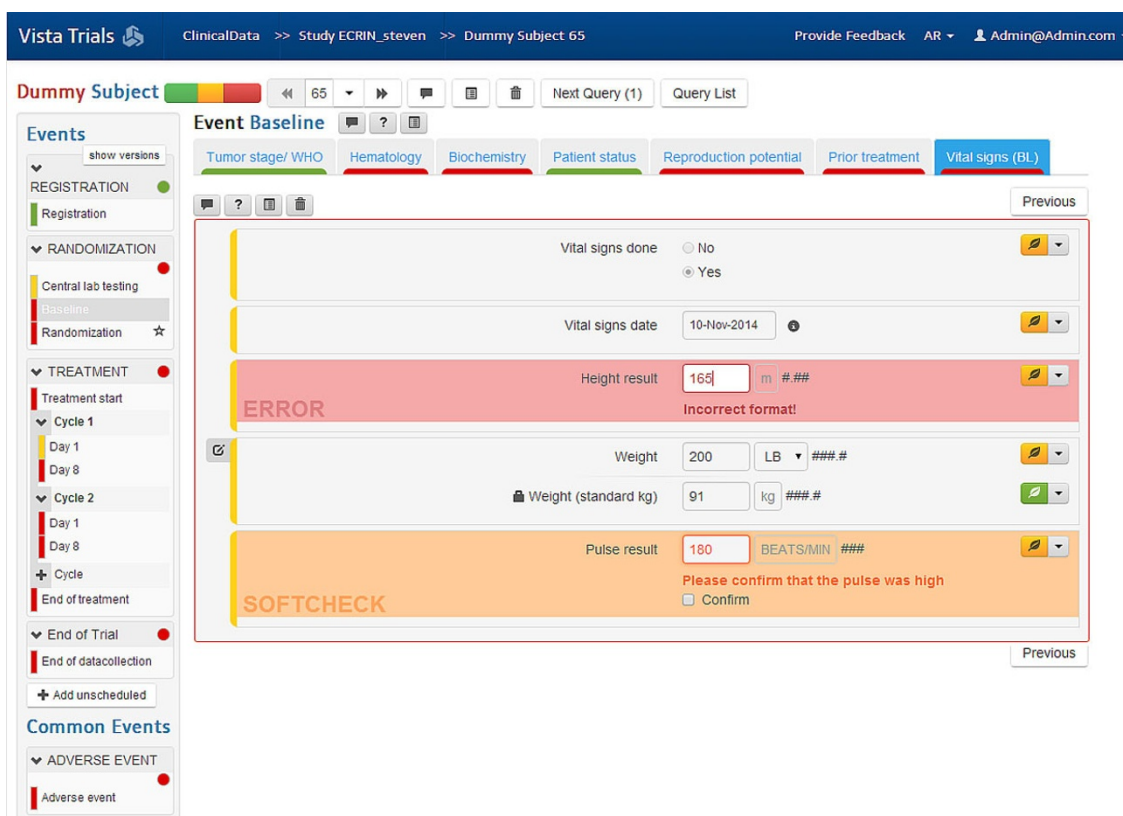
From 1st Clinical Research Informatics (CRI) Solutions Day  
Duesseldorf, Germany. 26-27 May 2014**Characterisation**

Tool, Clinical Data Management System, randomization.

**Description**

VISTA Trials is a professional, affordable and efficient Clinical Data Management System (CDMS) developed by the European Organisation for Research and Treatment of Cancer (EORTC). It will be available to research orga-

nizations looking for a solution to run their multinational clinical trials. VISTA Trials has been used by EORTC for many years and is now being upgraded to CDISC standards and ECRIN requirements. It is a fully integrated and web-based solution applicable to all therapeutic areas. VISTA Trials is composed of 4 modules built around different functionalities: TrialDesign for database and intelligent eCRF design (with built-in logic), Clinical



The screenshot shows the VISTA Trials web interface. At the top, the breadcrumb navigation is 'ClinicalData >> Study ECRIN\_steven >> Dummy Subject 65'. The main content area is titled 'Event Baseline' and contains several tabs: 'Tumor stage/ WHO', 'Hematology', 'Biochemistry', 'Patient status', 'Reproduction potential', 'Prior treatment', and 'Vital signs (BL)'. The 'Vital signs (BL)' tab is active. It displays a form for entering vital signs data. The form includes fields for 'Vital signs done' (radio buttons for 'No' and 'Yes'), 'Vital signs date' (10-Nov-2014), 'Height result' (165 m), 'Weight' (200 LB), 'Weight (standard kg)' (91 kg), and 'Pulse result' (180 BEATS/MIN). There are two error messages: a red one for 'Height result' stating 'Incorrect format!' and an orange one for 'Pulse result' stating 'Please confirm that the pulse was high' with a 'Confirm' checkbox. The left sidebar shows a list of events: 'REGISTRATION', 'RANDOMIZATION', 'TREATMENT', 'End of Trial', 'End of datacollection', 'Add unscheduled', 'Common Events', 'ADVERSE EVENT', and 'Adverse event'.

**Figure 1** VISTA Trials user interface. Display of ClinicalData module indicating a check for correctness of data input (in red).\* Correspondence: [caroline.gilotay@eortc.be](mailto:caroline.gilotay@eortc.be)

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Data for patient inclusion and randomization, electronic data capture, monitoring and data validation, Rights and Roles for access rights and user management, and Reports for data exports and metrics. Version management will be part of the system, making protocol amendments easy to handle. The system is based on CDISC standards, employing ODM as the backbone for the VISTA data model. Thanks to the ODM import and export elements, it is possible to handle any trial defined in that format, including libraries that will be a component of VISTA trials facilitating the management of user's standard CRFs. Dictionaries such as MedDRA and CTCAE as well as blinding and unblinding capacities will be integrated in the software in its second version.

VISTA Trials is GCP and 21CFR part 11 compliant, validated by a risk based approach following GAMP 5 guidance. Version 1.0 of the software is planned to be released by June 2015 with a SaaS deployment model.

### Status of development

In development, release expected by June 2015.

### Users

Academic research organisations.

### Links

<http://www.vistatrials.org/>

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